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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,258	11/24/2006	Qiwang Xu	CCPIT-1 (IEC040017PUS)	3347
26479	7590	03/26/2008		
STRAUB & POKOTYLO 620 TINTON AVENUE BLDG. B, 2ND FLOOR TINTON FALLS, NJ 07724			EXAMINER KRISHNAN, GANAPATHY	
			ART UNIT	PAPER NUMBER
			1623	
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			03/26/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,258	<b>Applicant(s)</b> XU ET AL.	
	<b>Examiner</b> Ganapathy Krishnan	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-7 and 11-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-7 and 11-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/07/01/06</u>   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The amendment filed 1/4/2008 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1-4 and 8-10 have been canceled.
2. New Claims 12-17 have been added.
3. Remarks drawn to IDS and rejections under 35 USC 112, second paragraph, 101, 102 and double patenting.

Claims 5-7 and 11-17 are pending in the case.

### **Information Disclosure Statement**

Document CN 1372931A is indicated as considered in the IDS based on the degree of relevancy indicated in the Search Report and IPER filed 9/27/2005.

### **The following rejections of record have been withdrawn:**

The rejection of Claims 1-4 and 8-10 under 35 U.S.C. 101 has been rendered moot by cancellation of the said claims.

The rejection of Claims 1-4 and 8-10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been rendered moot by cancellation of the said claims.

The rejection of Claims 1-4 and 8-10 under 35 U.S.C. 102(b) as being anticipated by Burton et al (US 5,217,962) has been rendered moot by cancellation of the said claims.

**The following rejections of record have been maintained:*****Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of Claims 1-10 provisionally on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/550,784 ('784) is being maintained for reasons of record.

Applicants have stated that they will address this rejection if and when copending '784 application issues.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 5-7 and 11-12 under 35 U.S.C. 102(b) as being anticipated by Burton et al (US 5,217,962) is being maintained for reasons of record.

Applicants have traversed the rejection arguing that:

1. Independent claim 5 is drawn to non-specific inflammation. Specific and non-specific inflammations are different. Specific inflammations are those mediated by cell or immune complex.

2. Non-specific inflammations may be caused by common factors like heat, insolation, crush injury, cold injury, blunt tearing etc. Chemical factors include acid and base burns. Since the mechanisms are different it is not obvious that a drug for treating specific inflammation can also act as an agent for treating non-specific inflammation.

Applicants' arguments have been considered but are not found to be persuasive.

Burton et al teaching of oral administration of N-acetyl glucosamine for the treatment of irritable bowel syndrome, caused by damage of the gastrointestinal tract by corrosive digestive juices, which is acidic. This reads on non-specific inflammation cause by chemical factors as recited in instant claim 5. The dosage for the said treatment is about 300mg to 10,000g per day (col. 2, line 65 through col. 3, line 3; col. 5, Example 1) and the N-acetyl glucosamine can be taken in the form of capsules (medicament; col. 6, lines 23-25). This teaching of Burton is seen to meet the limitations of instant claims 5-7 and 11-12. The recitation of the term non-specific is not seen to impart a patentable distinction.

**The following new rejections are made of record necessitated by amendment.**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Carlozzi et al (US 3,232,836).

Carlozzi et al teach the use of N-acetylglucosamine for the treatment (healing) of wounds of the body surface caused by trauma or surgery via administration of an effective amount of N-acetylglucosamine or a salt derivative thereof (col. 1, lines 22-25, 39-48; col. 1, line 67 through col. 2, line 2). Wounds include surgical incision (col. 2, lines 56-71). This is seen to be the same as a tear injury as instantly recited.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burton et al (US 5,217,962) in view of De Santis et al (Annals of Burns and Fire Disasters, 1997, vol. X(3), pages 1-6).

Burton's teaching is explained above. Burton's teaching is drawn to damage caused by acid (acid burn). De Santis, drawn to treatment of scars caused by burns, teaches that N-acetyl-D-glucosamine is a natural molecule and an active metabolite of UDP-N-acetylglucosamine, which is essential for the formation of the monomer of hyaluronic acid after conjugation with glycuronic acid (page 2, first full paragraph, last three lines) and the pliable and elastic nature of the scars caused by the burns is due to the association of substances on the production of hyaluronic acid, fibronectin and collagen (page 4, last paragraph). N-acetyl-D-glucosamine is one such substance.

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It would have been obvious to one of skill in the art at the time the invention was made to use N-acetyl-D-glucosamine in a method for treating burn and inflammation cause by cold injury since the treatment of closely related injuries on skin and gastrointestinal tract using N-acetyl-D-glucosamine is seen to be taught in the prior art.

One of skill in the art would be motivated to use N-acetyl-D-glucosamine in a method as instantly claimed since such injuries need the association of N-acetyl-D-glucosamine, a natural substance, for the production of hyaluronic acid for proper healing.

### ***Conclusion***

Claims 5-7 and 11-17 are rejected

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

/Shaojia Anna Jiang, Ph.D./

Supervisory Patent Examiner, Art Unit 1623